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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/341,821	09/01/1999	MICHAEL J. WARING	CV0244	5635

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T R FURMAN
BRISTOL MYERS SQUIBB COMPANY
100 HEADQUARTERS PARK DRIVE
SKILLMAN, NJ 08558

EXAMINER	
GHALI, ISIS A D	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/341,821	WARING ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-10,13-15 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,13-15 and 17-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The receipt is acknowledged of applicants' response, filed 04/07/2004.

Claims 1-6, 8-10, 13-15, 17-20 are pending in the application.

Specification

1. The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.
(b) CROSS-REFERENCE TO RELATED APPLICATIONS.
(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
(d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
(e) BACKGROUND OF THE INVENTION.
(1) Field of the Invention.
(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) BRIEF SUMMARY OF THE INVENTION.
(g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
(h) DETAILED DESCRIPTION OF THE INVENTION.

(i) CLAIM OR CLAIMS (commencing on a separate sheet).
(j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
(k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Response to Arguments

With regard to the objections made to the specification above, applicants have failed to insert heading for the application sections as required by guideline provided by 37 CFR 1.77(b).

Claim Rejections - 35 USC § 102

2. Claims 1-4, 13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,976,223 ('223).

The instant claim 1 reads on an aerosol container containing gel. Instant claim 13 reads on treating wound by discharging onto the wound a gel from an aerosol container. The dependent claims 2-4 and 17 recite the gel comprising hydrocolloid (claims 2 and 17), gelling agent (claim 3) and glycol (claim 4).

US '223 disclosed an aerosol container containing gel, which reads on claim 1, and comprising carboxymethyl cellulose, gelling agent and alginate, which reads on claims 2, 3 and 17. The gel comprises polyethylene glycol, which reads on claim 4 (col.6, lines 28-31, 34, 48, 63-65; col.7, lines 29-30; col.9, lines 20-23, 45-48, 51-55). The aerosol containing gel used to treat burns, which reeds on claim 13 (col.9, lines 20-55). The aerosol is provided by mechanical stream break up features, i.e. self-sealing

(col.2, lines 65-67). The aerosol disclosed by the reference is not a single dose container as implied by the effort made to avoid contamination of the contents during use.

The limitations of claims 1-4, 13 and 17 are met by US '223.

Response to Arguments

Applicant's arguments filed 04/07/2004 have been fully considered but they are not persuasive.

Applicants traverse the 102 rejection above by arguing that the purpose of the package of Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. According to Jass et al., only the lower chamber of the outer container is pressurized with a gas through a self-sealing plug in the container bottom. With respect to some implication read into Jass et al., applicants submit that Jass et al. does not address the avoidance of contamination during use. Rather, the avoidance of contamination appears to be with respect to storage.

In response to the above argument, the examiner position is the rejected claims are directed to an aerosol container containing gel and method of treating wound comprising using the aerosol, and the cited reference teaches an aerosol containing gel for treating wound. The reference disclosed the aerosol is self-sealing, col.4, line 27; and aerosol contains multiple doses. The cut off of the flow as well as the self-sealing properties of the aerosol inherently prevent contamination of the content of the aerosol.

In any event, avoidance of contamination during use is not recited in the rejected claims under 102 rejection. Further, regarding the structure of the aerosol disclosed by the reference with only the lower part pressurized, this feature is not recited feature in any of the claims.

Claim Rejections - 35 USC § 103

3. Claims 5, 6, 10, 14, 15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '223 in view of EP 666 081 ('081).

The teaching of US '223 are disclosed under 102 rejection above.

US '223 does not teach the same composition of the gel as claimed in claim 5. The reference does not teach the gel is sterile as claimed in claims 6, 10 and 15 or the viscosity of the gel as claimed in claim 18. The reference does not teach the wound to be treated is a sinus wound as claimed in claim 14.

No superior and unexpected results of record to show the criticality in treating of sinus wound using the instant composition.

EP '081 teaches gel wound dressing comprising material comprising:

a) from about 0.05% to 10% by weight of natural gelling agent;

b) from about 1.0% to 10% by weight of hydrocolloid;

c) from about 5.0% to 30.0% by weight of an alkylene glycol and

d) at least 50% by weight of water.

The above ingredients read on claim 5. The wound dressing is packaged and sterilized, which reads on claims 6, 10 and 15. The gel composition of the reference can be

extruded in the form of gel through a nozzle (page 2, lines 20-24; page 3, lines 14-18). The gel of the reference has viscosity of 50-800 Pas, which reads on claim 18, (page 2, lines 54-55). The reference disclosed the gel conforms readily to the shape of the wound particularly when the wound includes a cavity, and that teaching suggests treating sinus wound (page 2, lines 8-9).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver an aerosol containing gel wound dressing as disclosed by US '223, and replace the gel by the sterile gel composition disclosed by EP '081, motivated by the teaching of EP '081 that the gel composition has a viscosity that reduces the flow of the gel from the wound site and conforms readily to the shape of the wound particularly when the wound includes a cavity, with reasonable expectation of the delivered aerosol containing gel to treat wounds, and in particular sinus wounds with success.

Response to Arguments

Applicant's arguments filed 04/07/2004 have been fully considered but they are not persuasive.

Applicants traverse the above 103 rejection of claims 5, 6, 10, 14, 15 and 18 as being unpatentable over Jass et al. in view of EP 666 081 ('081) by arguing that the invention is not simply substituting one liquid in any aerosol device for another. The focus of the invention in Jass et al. is to separately store a plurality of flowable substances in a single package from which such substances may be dispensed. Since

that is the focus of the invention, there is no reason other than hindsight to substitute the composition of the '081 document for the composition of Jass et al. Further, while the composition in the '081 document is a gel, the '081 document does not provide that which is missing in Jass et al. as noted above.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., storage of a plurality of flowable substances in a single package) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). EP '081 is relied upon for teaching the gel composition of the wound dressing. EP '081 teaches gel, as applicants admit. Applicants claim an aerosol containing multiple doses gel, not claiming if the doses are separate or not. Even if they claim the multiple doses are not separate, there are no superior and unexpected results of record to show the criticality of the claimed multiple doses over the separately stored multiple doses of the prior art. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

4. Claims 8, 9,19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,059,187 ('187) in view of US '223.

US '187 teaches a method for providing an aerosol container and method for cleaning the wound including the steps of introducing the wound cleaning material though an opening into a pouch and then the opening is closed by a valve, the container is then sterilized and the propellant is introduced into the can (abstract; col.3, lines 1-10; col.5, lines 8-21).

US '187 does not teach the aerosol vessel containing gel.

The teachings of US '223 are discussed under 102 rejection above, an aerosol containing wound treating gel.

Accordingly, it would have been obvious for one having ordinary skill in the art at the time of the invention to provide an aerosol for wound treating produced by the method disclosed by US '187, and replace its contents by wound-treating gel as disclosed by US '223, motivated by the teaching of US '223 that gel provides a soothing strippable gel bandage that excludes air, with reasonable expectation of the delivered aerosol containing gel to treat wound with success.

Response to Arguments

Applicant's arguments filed 04/07/2004 have been fully considered but they are not persuasive.

Applicants traverse the 103 rejection of claims 8, 9, 19 and 20 as being unpatentable over US Patent No. 5,059,187 ("Sperry et al.") in view of Jass et al. by arguing that Sperry et al. teach away from the present invention in at least two important ways. First, Sperry et al. do not teach or suggest a dispensing vehicle that contains multiple doses of wound-treating material. Instead, Sperry et al. teach the container contains enough wound cleaning solution to irrigate the average wound or abrasion. Thus, nothing in Sperry et al. suggests a wound gel dispenser capable of dispensing multiple doses while keeping the wound gel contents reasonably free of contaminants. A second way in which Sperry et al. teach away from the present invention is in the fact that Sperry et al. disclose a method of dispensing liquid, not gel, to a wound. This method lacks the complicating factors of dispensing a gel that is in gel-form within the container. Further, Sperry et al. do not make up for the deficiencies of Jass et al. as noted above.

In response to the first applicant's argument that Sperry et al. do not teach the multiple doses of the wound treating material, the examiner position is that the reference is relied upon for the solely teaching of the method of making the aerosol. It is noted that the features upon which applicant relies (i.e., aerosol containing multiple does) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The rejected claims 8 and 9 are directed to method of making an aerosol, and Sperry's reference teaches the claimed method of making an aerosol. The reference further teaches sterile

content of the aerosol which is not contaminated at use, as desired by applicant. Regarding the second applicants' argument that the reference teaches dispensing liquid and not gel, the examiner position is, the reference is relied upon for solely teaching the method of making of the aerosol vessel, and one cannot show nonobviousness by attacking the references individually where the rejections are based on combination of references. *See In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, the rationale to modify the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art and the reason to modify the reference may often suggest what the applicant has done. Thus, the secondary reference does not need to teach the gel that is taught by the primary reference.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Isis Ghali
Examiner
Art Unit 1615

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600